

Food and Drug Administration, HHS

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(2) *Cats*. For use in cats 6 weeks of age and older as follows:

(i) *Amount*. Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) *Indications for use*. To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae *Dirofilaria immitis* for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms *Ancylostoma tubaeforme* and *A. braziliense*.

[67 FR 11230, Mar. 13, 2002]

§ 520.1194 Ivermectin drench.

(a) *Specifications*. Each milliliter of 0.08 percent (weight per volume) micellar solution contains 0.08 milligram of ivermectin.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.344 of this chapter.

(d) *Conditions of use*—(1) *Amount*. 3.0 milliliters (2.4 milligrams of ivermectin) per 26 pounds of body weight (or 200 micrograms per kilogram of body weight).

(2) *Indications for use*. It is used in sheep for treatment and control of the adult and fourth-stage larvae of the following parasites of sheep: gastrointestinal roundworms (*Haemonchus contortus*, *H. placei* (adults only), *Ostertagia circumcincta*, *Trichostrongylus axei*, *T. Colubriformis*, *Cooperia oncophora* (adults only), *C. curticei*, *Oesophagostomum columbianum*, *O. venulosum* (adults only), *Nematodirus battus*, *N. spathiger*, *Strongyloides papillosus* (adults only), *Chabertia ovina* (adults only), *Trichuris ovis* (adults only)), lungworms (*Dictyocaulus filaria*); and all larval stages of the nasal bot *Oestrus ovis*.

(3) *Limitations*. It is used as a drench in sheep only. Do not treat sheep within 11 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian

for assistance in the diagnosis, treatment, and control of parasitism.

[53 FR 27958, July 26, 1988, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.1195 Ivermectin liquid.

(a) *Specifications*. Each milliliter contains 10 milligrams of ivermectin.

(b) *Sponsor*. See Nos. 050604, 051259, 058829, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 200 micrograms per kilogram of body weight as a single dose by stomach tube or as an oral drench.

(2) *Indications for use*. For the treatment and control of large strongyles (adult) (*Strongylus equinus*), (adult and arterial larval stages) (*Strongylus vulgaris*), (adult and migrating tissue stages) (*Strongylus edentatus*), (adult) (*Triodontophorus* spp.); small strongyles, including those resistant to some benzimidazole class compounds (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicodontophorus* spp., *Cylicostephanus* spp.); pinworms (adult and fourth stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostongylus axei*); large mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and fourth stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

(3) *Limitations*. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 34637, Sept. 14, 1987, as amended at 53 FR 51273, Dec. 21, 1988; 62 FR 63270, Nov. 28, 1997; 63 FR 38474, July 17, 1998; 66 FR 7579, Jan. 24, 2001; 66 FR 63166, Dec. 5, 2001]

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablet.

(a) *Specifications*. Each chewable tablet contains either 68 micrograms (µg) of ivermectin and 57 milligrams (mg) of pyrantel (as pamoate salt), or 136 µg

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and 114 mg, or 272 µg and 227 mg, respectively.

(b) *Sponsors.* See Nos. 050604 and 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* A minimum of 6 µg of ivermectin and 5 mg of pyrantel (as pamoate salt) per kilogram (2.72 µg and 2.27 mg per pound) of body weight.

(ii) *Indications for use.* To prevent canine heartworm disease by eliminating the tissue larval stages of *Dirofilaria immitis* for up to a month (30 days) after infection and treatment and control of adult ascarids *Toxocara canis* and *Toxascaris leonina*, and adult hookworms *Ancylostoma caninum*, *A. braziliense*, and *Uncinaria stenocephala*.

(iii) *Limitations.* Use monthly. Recommended for dogs 6 weeks of age and older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[58 FR 8542, Feb. 16, 1993, as amended at 61 FR 15186, Apr. 5, 1996; 61 FR 59004, Nov. 20, 1996; 62 FR 63270, Nov. 28, 1997; 66 FR 35756, July 9, 2001]

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 130 days), of gastrointestinal roundworms *Haemonchus placei*, *Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Nematodirus helvetianus*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*; lungworms *Dictyocaulus viviparus*; grubs *Hypoderma* spp.; sucking lice *Linognathus vituli*, *Solenopotes capillatus*; mange mites *Psoroptes ovis*, *Sarcoptes scabiei*, and ticks *Amblyomma americanum*.

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(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 67452, Dec. 23, 1996, as amended at 62 FR 63270, Nov. 28, 1997; 65 FR 45876, July 26, 2000]

§ 520.1204 Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgit suspension.

(a) *Specifications.* Each five milliliters of suspension of the drug contains: 100 milligrams of kanamycin as the sulfate, 0.033 milligram of aminopentamide hydrogen sulfate, 25 milligrams of pectin, 250 milligrams of bismuth subcarbonate, and 500 milligrams of activated attapulgit.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is administered orally to dogs for the symptomatic relief of acute bacterial diarrhea caused by kanamycin-susceptible organisms.

(2) The drug is recommended for use at the rate of one teaspoonful (5 milliliters) of suspension per 20 pounds of body weight every 8 hours. Animals weighing under 10 pounds should be given one-half the above amount every 8 hours. The initial dose should be twice the amount of a single dose. Maximum dosage should not exceed three times the recommended dose.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988; 56 FR 8710, Mar. 1, 1991; 64 FR 403, Jan. 5, 1999]

§ 520.1205 Kanamycin sulfate, pectin, bismuth subcarbonate, activated attapulgit tablets.

(a) *Specifications.* Each tablet contains 100 milligrams of kanamycin (as the sulfate), 25 milligrams of pectin,